

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P O Box 1450 Alexandria, Virgiria 22313-1450 www.uspio.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/924,428	08/07/2001	Lei Wu	4718420005000	3614
25225 7590 07/07/2009 MORRISON & FOERSTER LLP 12531 HIGH BLUFF DRIVE			EXAMINER	
			CHEU, CHANGHWA J	
	SUITE 100 SAN DIEGO, CA 92130-2040		ART UNIT	PAPER NUMBER
			1641	
			MAIL DATE	DELIVERY MODE
			07/07/2009	PAPER

## Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

### Application No. Applicant(s) 09/924,428 WU ET AL. Office Action Summary Examiner Art Unit JACOB CHEU 1641 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 03 February 2009. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 122-143 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) \_\_\_\_\_ is/are allowed. 6) Claim(s) 122-143 is/are rejected. 7) Claim(s) \_\_\_\_\_ is/are objected to. 8) Claim(s) \_\_\_\_ \_\_ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are; a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abevance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner, Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) ☐ All b) ☐ Some \* c) ☐ None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). \* See the attached detailed Office action for a list of the certified copies not received. Attachment(s)

1) Notice of References Cited (PTO-892)

Notice of Draftsperson's Patent Drawing Review (PTO-948)

Information Disclosure Statement(s) (PTO/SB/08)
 Paper No/s Wail Date

Interview Summary (PTO-413)
 Paper No(s)/Mail Date.

6) Other:

5) Notice of Informal Patent Application

Application/Control Number: 09/924,428 Page 2

Art Unit: 1641

# DETAILED ACTION Status of Claims

 Applicant's amendment filed on 2/3/2009 has been received and entered into record and considered.

The following information provided in the amendment affects the instant application:

- 1. Claims 1-121 have been cancelled.
- 2. Claims 140-143 have been added to the instant application.
- 3. Currently, claims 122-143 are under examination.
- The rejections of claims 122-132 under 35 U.S.C. 112, second paragraph, are withdrawn because of the amendments.
- The rejections of claims 14, 33-34 and 118-119 are moot due to cancelling of these claims.
- 4. The rejections of claims 133-135, 138-139 under 35 U.S.C. 103(a) as being unpatentable over Kaye et al. in view of Wu et al., Hasegawa et al. (US 5858125) and Hungerford et al. (US 20020034042) are withdrawn because none of the references teaches using a binding partner comprising a cell, a cellular organelle, a virus or an antibody. Accordingly, the dependent claims 136-137 are withdrawn. However, Examiner has provided Kauver et al. reference (US 6492125) for immobilizing binding partner antibody on beads for combinatorial library screening (See below).
- 5. A new ground of rejection against claims 122-143 is set forth in this Office Action.

#### Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1641

 Claim 136 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as

the invention.

With respect to claim 122, last line, "a pattered magnetic material" is not clear. It is not clear whether this feature is related to the photorecognizable identification. In view of the instant invention, it is believed that Applicant uses "photorecognizable coding pattern" on the microdevice for purpose of identification. The magnetic materials on the microdevice are used for facilitation purpose, e.g. magnetic forces, for further characterization. It is not clear whether this patterned magnetic materials is also "photorecognizable".

Similarly, it is not clear what is the "encoding feature" recited in claims 125, 140-1141 in

relation to the usage of magnetic force for further identification purpose.

With respect to claim 136, it is not clear what is the "moiety-microdevice complex".

Please specify and clarify.

#### Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all
obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made. Application/Control Number: 09/924,428 Page 4

Art Unit: 1641

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- Considering objective evidence present in the application indicating obviousness
  or nonohyiousness
- Claims 133-135, 138-139 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaye et al. in view of Wu et al., Hasegawa et al. (US 5858125), Hungerford et al. (US 20020034042) and Kauver et al. (US 6492125).

Kave et al. teach a microdevice for combinational library screening. Kave et al. teach that the microdevice comprises a substrate, a photorecognizing coding pattern on said substrate, and a binding partner for binding target molecule of interest (See page 6, line 5-15; page 2, line 1-5; Figure 2 and 5). The microdevice can be conjugated with beads where the interest of target is immobilized thereon for screening (See page 19, line 12-20; Figure 7, particular Figure 7b)(emphasis added). The target molecules immobilized on the microdevice, includes peptide, compounds, or oligonucleotides suitable for combinatorial synthesis or analysis (See page 1, first paragraph; page 3-4; page 18, line 15-20). These peptides, compounds or oligonucleotides are inherent binding partners capable of being manipulated. The photorecognizable code taught by Kaye et al. consists of different shapes and forms, including hollows, grooves, or notches, which are holes not penetrating through the entire depth of the substrate (See page 6, line 5-15; Figure 2 and 5; Particular Figure 2, second example, holes not penetrated through the substrate)(emphasis added). Kaye et al. also teach use of silicon layer for the substrate (See Abstract). With respect to the dimensions, the microdevice taught by Kaye et al. can be within from 1 to 500 microns ranges (See page 9, last paragraph). The microdevice of Kave et al. does not comprise an anodized metal surface layer (See page 10-15; Figure 25;). However, Kaye et al. do not disclose the features of having magnetic material on the microdevice. Furthermore, Kay et al. do not explicitly teach using material, such as nickel or CoTaZr alloy for the substrate layer. Moreover, Kaye et al. teach using peptide or oligonucleotide as binding partner on the microdevice, but not with antibody.

Kauver et al. teach using combinatorial library screening for useful compounds or ligands based upon manipulation of binding moiety between two molecules, e.g. antigenantibody or peptide-antibody or DNA-DNA. Kauver et al. teach immobilizing binding partner, such as antibody on beads for library screening (Col. 3, line 65 to Col. 4, line 15). Immobilizing a binding moiety, e.g. antibody on the beads, for manipulation is considered a routine practice in the combinatorial library screening.

Wu et al. teach immobilizing binding partner capable of being manipulated on the beads having magnetic materials (See Figure 4). Wu et al teach using magnetic force or means for detection or separation of analyte from the sample. Supra. It is known and common practice in the art using magnetic means for detection analyte.

Hasegawa et al. teach that the CoTaZr alloy provides advantage for increasing magnetoresistance sensitivity for magnetic sensor (Col. 2, line 35-41).

Hungerford et al. teach that the nickel-zine ferrite also provides advantage for increasing magnetoresistive sensor (See Section 0036).

Therefore, it would have been prima facie obvious to one ordinary skill in the art at the time the invention was made to have motivated Kaye et al. to immobilize antibody on the microdevice as taught by Kauver, and apply the magnetic beads as taught by Wu et al. for screening target molecules in a combinatorial library screening. One ordinary skill in the

Application/Control Number: 09/924,428

Art Unit: 1641

art would have been motivated to immobilize antibody on the microdevice in order to target candidate of specific antigen(s) corresponding to the immobilized antibody on the microdevice. Such practice is considered routine practice in the combinatorial library screening. In addition, one ordinary skill in the art would have been motivated to use the magnetic means in order to improve efficiency of detection, separation or isolation of target molecules from the sample.

Furthermore, it would have been obvious to one ordinary skill in the art at the time the invention was made to have motivated Kay and Wu et al. to use either nickel metal or CoTaZr alloy as taught by Hasegawa or Hungerford et al. in order to take the advantage of enhancing the sensitivity of magnetic means detection.

With respect to claims 134-133, Kaye teach using fluorescent or phosphorescent materials substance for detection purpose (See page 15, line 20).

With respect to claims 138-139, Kaye et al. teach that the thickness of the microdevice is about 10 microns (See page 21, last paragraph).

With respect to claim 133, Wu et al. teach immobilizing antibody on the magnetic beads (See Figure 3; Abstract).

 Claims 136-137 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaye et al. in view of Wu, Hasegawa et al. and Hungerford et al. Kauver et al. and further in view of Zhou et al.

Kaye, Wu, Hasegawa, Kauver and Hungerford et al. references have been discussed but are silent in teaching use of chips for analysis.

Zhou et al. teach a biochip to detect manipulation of micro-particles and biological materials for economy and time-saving purposes (Col. 2, line 55-65).

Art Unit: 1641

Therefore, it would have been prima facie obvious to one ordinary skill in the art at the time the invention was made to have motivated Kaye, Wu, Hasegawa et al. Kauver et al. and Hungerford et al. to immobilize the microdevice on the surface of the chip array as taught by Zhou et al. for high throughput analysis. One ordinary skill in the art would have been motivated to apply the microdevice for mass high throughput analysis by the format of array on biochip to take the advantage of economy and time-saving.

The following reference has been considered but is not used for prior art rejection. Lam
et al. Chem Rev. 1997 Vol. 97, page 411-448.

#### Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JACOB CHEU whose telephone number is (571)272-0814. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on 571-272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Application/Control Number: 09/924,428 Page 8

Art Unit: 1641

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jacob Cheu/ Examiner, Art Unit 1641